



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

100

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/483,837 01/17/00 SHARMA

S 70025-9902-1

005179 HM22/0214
PEACOCK MYERS AND ADAMS P C
P O BOX 26927
ALBUQUERQUE NM 87125-6927

EXAMINER

WESSENDORF, T

ART UNIT

PAPER NUMBER

1627
DATE MAILED:

10
02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/483,837

Applicant(s)

Shubh

Examiner

T. Wessendorf

Group Art Unit

1627



☒ Responsive to communication(s) filed on 1/17/01

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 35-62 is/are pending in the application

Of the above, claim(s) 35-40 and 60-62 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 41-59 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1627

Applicant's election of Group II, claims 41-59 in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 35-40 and 60-62 are withdrawn from further consideration pursuant to 37 CAR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CAR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It claims priority to S.N. 08/476,652, filed on 6/7/95 which is inconsistent with the priority claim at page 1 of the instant specification. The specification claims priority to S.N. 08/660,697 filed on 6/5/96 as per Prel. Amendment of 1/17/00.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Art Unit: 1627

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 41-59 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specifically asserted utility or a well established utility.

The claimed combinatorial library fails to comply with the above 101 statute that a claim to a product or composition be new and useful. The claimed combinatorial library, as broadly interpreted, reads on naturally occurring catalytic antibodies, for example, that represent or generated by the immune system. This combinatorial library is nothing more than a collection of known, existing compounds and therefore can not be considered new. Furthermore, the specification asserts the utility of the combinatorial library for screening. But screening is not a specific utility. As with all collections, screening are done, to isolate a specific compound that yields a specific utility. A patent application is a not a hunting license rather, a reward for the successful accomplishments of a search. An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the specific invention is

Art Unit: 1627

in fact "useful" in a patent sense. A collection or mixture of different compounds does not have a specifically identified utility, rather an invention whose specific utility requires "intermediate" or "for research purposes" which are not helpful in determining if applicant has identified a specific utility for the claimed collection or library . (See MPEP 2107).

Claims 41-59 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specifically asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 41-59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific library that binds to rhenium metal, does not reasonably provide enablement for any type of combinatorial library with at least three residues, two of which form a metal-ion binding domain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Art Unit: 1627

The scope of enabling disclosure provided in the specification e.g., page 124, Example 67 is not commensurate in scope with the broadly, incompletely identified components of the claimed library. The claimed library covers too numerous variables for which the specifically designed library would not provide as enabling disclosure. The specification merely provides the known multiple synthesis of the library but does not identify a specific components of the library and more importantly, the conditions necessary for the bioassays, as asserted. The claim is nothing more than an invitation to experiment.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1). The following language "synthesized on solid phase"., "forming a metal ion-binding domains"; "cleavable bond attaching the sequence to solid phase" all relate to method of synthesis rather than to the claimed library or collection of

Art Unit: 1627

compounds. The term 'unique' within the claimed context, is indefinite as to the basis or standard by which said sequence is categorized as unique. Also, the term domain, within the claimed context, fails to set the metes and bounds of the claimed invention. A sequence of one residue is indefinite since a sequence contains more than one residue.

2). Claim 45 recitation of 'removable ' is indefinite for failing to ascertain the claimed invention with precision.

3). The use of abbreviations e.g., Trt renders the claim indefinite. It is suggested that applicants recite for the complete name e.g., trityl. E.g., claim 46.

4). The terms 'outside' and 'diversity' fail to ascertain the claim with precision, especially since the claimed library does not contain any structure. E.g., claims 47-48.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Art Unit: 1627

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 41, 45, 46, 47, 50, 54, 55, 59 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Francis et al [(J.Am. Chems.Soc.) (I) or Current Opinion in Chemical Biol.(II)]

The broadly recited combinatorial library of peptide sequence that contains a metal-ion binding portion is fully met by the combinatorial library of Francis containing specific peptide components that bind to the specifically recited different metals. See pages 8983-8984.

See the entire disclosure of Francis II specifically at e.g., page 422, col. 2 up to page 428. Therefore, the library of Francis anticipates or renders obvious the claimed invention. Claims 41-59 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kay et al (5,498,538).

Art Unit: 1627

The broadly recited combinatorial library of peptide sequence that contains a metal-ion binding portion is fully met by the combinatorial library of Kay containing specific peptide components that bind to the specifically recited different metals See e.g., col. 47, line 55 up to col. 56. Therefore, the library of Kay anticipates or renders obvious the claimed invention.

Certain papers related to this application may be submitted to Art Unit 1627 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 O.G. 61 (November 16, 1993) and 1157 O.G. 94 (December 28, 1993) (see 37 C.F.R. 1.6(d)). The official fax telephone numbers of the Group are (703)308-7924. NOTE: If applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Mon. to Fri. from 8 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat Ph.D.,

Art Unit: 1627

can be reached on (703) 308-0570. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



T. Wessendorf
Patent Examiner
Art Unit 1627
2/12/01